510(k) Summary

DEC 2 3 2013

Date:	24 July 2013
Sponsor:	SIGNUS Medizintechnik GmbH Industriestrasse 2 D-63755 Alzenau, GERMANY Tel. + 49 (0) 6023 9166-136 Fax + 49 (0) 6023 9166-161 Url: http://www.signus-med.de
Contact Person:	Joachim Schneider, Quality Management/Regulatory Affairs
Trade Names:	ASCOT®
Device Classification	Class II
Common Name:	Anterior cervical plate system
Classification Name:	Appliance, fixation, spinal intervertebral body
Regulation:	888.3060
Device Product Code:	KWQ
Device Description:	ASCOT® is an anterior cervical plate and screw system. Plates offered in a variety of sizes to accommodate anatomic requirements. Fixed and variable angle screws are available in numerous length/diameter combinations. In addition, a center graft screw is offered.
Intended Use:	ASCOT® is intended for anterior cervical fixation (C2-C7) for the following indications: degenerative disc disease (as defined by neck pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies), spondylolisthesis, trauma (i.e., fracture or dislocation), spinal stenosis, deformities or curvatures (i.e., scoliosis, kyphosis and/or lordosis), tumor, pseudarthrosis and failed previous fusion.
Materials:	The ASCOT® implant components are manufactured from titanium alloy (Ti-6Al-4V ELI) as described by ASTM F136.
Predicate Devices:	TOSCA® (K043082) TOSCA® II (K080815) VERTEBRON SCP™ (K051815 & K062110) Uniplate™ (K042544)
Performance Data:	Mechanical testing of the worst case ASCOT® was performed according to ASTM F1717 and included static and dynamic compression bending and static torsion. The mechanical test results demonstrate that the ASCOT® device performance is substantially equivalent to the predicate devices.

Technological Characteristics:

ASCOT® possesses the same technological characteristics as the predicate devices. These include:

- performance (as described above),
- basic design (plate and screw system),
- material (titanium alloy), and
- sizes (component dimensions are within the ranges offered by the predicates).

Therefore the fundamental scientific technology of the ASCOT® device is the same as previously cleared devices.

Conclusion:

The ASCOT® devices possess the same intended use and technological characteristics as the predicate devices. Therefore the ASCOT® is substantially equivalent for its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

December 23, 2013

SIGNUS Medizintechnik GmbH
% Karen E. Warden, Ph.D.
BackRoads Consulting, Incorporated
8202 Sherman Road
Chesterland, Ohio 44026

Re: K132310
Trade/Device Name: ASCOT®
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal intervertebral body fixation orthosis
Regulatory Class: Class II
Product Code: KWQ
Dated: November 13, 2013
Received: November 19, 2013

Dear Dr. Warden:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Ronald P. Jean -S for

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Section 7 - Indications for Use Statement

510(k) Number: K132310

Device Name: **ASCOT®**

Indications for Use:

ASCOT® is intended for anterior cervical fixation (C2-C7) for the following indications: degenerative disc disease (defined as neck pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies), spondylolisthesis, trauma (i.e., fracture or dislocation), spinal stenosis, deformities or curvatures (i.e., scoliosis, kyphosis and/or lordosis), tumor, pseudarthrosis and failed previous fusion.

Prescription Use X OR Over-the-Counter Use_____

(Per 21 CFR 801.109)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Anton E. Dmitriev, PhD

Division of Orthopedic Devices